REMARKS

Claims 1-16 are pending in this application. Claims 1-13 have been amended, and claims 14-16 are newly presented. No new matter has been added. In view of the amendments and the following remarks, reconsideration and further examination of this application are respectfully requested.

Initially, Applicants note that a number of minor clarifying and other editorial amendments have been made to the specification and abstract to facilitate further examination. No new matter has been added. The changes to the specification and abstract are submitted in the form of a substitute specification and abstract. Also enclosed is a "marked-up" copy of the original specification and abstract to show the changes that have been incorporated into the substitute specification and abstract. The enclosed copy is entitled "*Version with Markings to Show Changes Made*."

On page 2 of the Office Action, the Examiner rejected claims 1-13 under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants have amended claims 1-13 in order to resolve the indefinite aspects identified by the Examiner, and to otherwise comply with the requirements of the statue. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Also, on page 2 of the Office Action, claim 11 was rejected under 35 U.S.C. §101 as claiming a portion of the body and, therefore, being directed to non-statutory subject matter. Claim 11 has been amended to include the recitation suggested by the Examiner. In particular, amended claim 11 recites that the tubular endoprosthesis *is adapted for placement* within the duct. Therefore, reconsideration and withdrawal of the rejection are requested.

On pages 3-5 of the Office Action, original claims 1-9, 11, and 12 were rejected under 35 U.S.C. §102(b) as being anticipated by Garrison et al. (U.S. 6,425,916; hereinafter "Garrison"). Claims 1, 2, 4, and 11-13 were rejected under 35 U.S.C. §102(b) as being anticipated by Fogarty et al. (U.S. 6,939,365; hereinafter "Fogarty"). Claims 1-3 and 11-13 were rejected under 35 U.S.C. §102(b) as being anticipated by Vesely (U.S. 6,530,952), and claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Vesely. These rejections are

respectfully traversed and, in any event, believed to be inapplicable to the amended and new claims for at least the following reasons.

Amended independent claim 1 recites a kit designed to be implanted within a duct. The kit comprises: a tubular endoprosthesis and a prosthetic valve adapted to be implanted in, and withdrawn from the tubular endoprothesis. The prosthetic valve includes a *resilient* carrier frame, which is *radially deformable in an elastic manner* relative to a central axis of the tubular endoprosthesis between a deployed position, in which it rests against the tubular endoprosthesis, and a folded position. The carrier frame is *biased toward the deployed position.* A flexible shutter is attached to the carrier frame, and deformable between an obstruction position in which it is *extended transversely,* and a release position in which it is *contracted transversely* to allow a fluid to flow through the carrier frame. The prosthetic valve further includes *integrated* centripetal compression means for *compressing the carrier frame from the deployed position towards the folded position.* Amended independent claim 12 recites a method of implanting a kit having the above-mentioned features.

Initially, Applicants note that the kit and corresponding method of the present invention enable the prosthetic valve to be easily removed, without major surgical intervention. For example, the arrangement and configuration of the carrier frame, shutter, and integrated centripetal compression means facilitate transluminal removal of the valve (Specification, p. 2 and 7; Figs. 5 and 6). It is submitted that the references of record fail to disclose a kit having the above-mentioned features, and that the absence of such features is consistent with the inability to provide the aforementioned advantage of the present invention.

Garrison discloses a kit including a cardiac valve (6,6C) attached to a valve displacer (8) (Figs. 9, 10, and 30). The Examiner asserts that the expandable support structure (26) and valve portion (38) of Garrison respectively correspond to the carrier frame and the flexible shutter of the present invention. However, the expandable support structure (26) moves from the collapsed (folded) position illustrated in Figures 4 and 10, to the expanded position illustrated in Figures 5 and 9 (Col. 5, lines 20-22). A catheter is necessary to deploy the support structure such that it rest against the tubular endoprothesis (8) (Col. 6, lines 36-38). In other words, the support structure (26) of Garrison is <u>not</u> *biased toward a deployed* (or expanded) position, as specifically required by claim 1. In addition, claim 1 requires *a flexible shutter* that is deformable between an obstruction position in which it is *extended transversely*, and a release position in which it is

contracted transversely. Garrison, on the other hand, discloses a valve portion (38) having a *plurality* of leaflets (39) which appear to *converge and diverge* to open and close the duct (See Figures 10 and 11). Thus, the Examiner's reliance on the plurality of leaflets disclosed by Garrison as corresponding to the flexible shutter recited in claim 1 is clearly misplaced. Further, claim 1 recites integrated centripetal compression means for compressing the carrier frame *from the deployed position toward the folded position*. The Examiner has indicated that protrusions (34), barbs (100), elongate member (30), and posts (32) of Garrison each correspond to the integrated centripetal compression means of the present invention. However, since the alleged carrier frame (support structure 26) is biased toward the folded position, it follows that components identified by the Examiner do not compress the carrier frame from the deployed position toward the folded position, as required by claim 1.

Forgarty discloses a prosthetic valve (68) implanted in a tubular endoprothesis (2). The Examiner asserts that Fogarty discloses the carrier frame of the present invention, without specifically identifying which portion the valve (68) illustrated in Figure 84 corresponds to the recited carrier frame. Although, Figure 84 illustrates the valve (68) in a deformed condition, Fogarty does not disclose a *resilient* carrier frame which is *radially deformable in an elastic manner* between a deployed position, and a folded position, as specifically required by claim 1. Figures 82-84 suggest that the valve frame is made of a *rigid* material since the valve is "crushed" by operation of the illustrated lever device (324) (Col. 14, lines 29-30). There is no indication that the valve frame of Fogarty is resilient or elastically deformable. Also, in contrast to the *transversely expanding and contracting flexible shutter* of claim 1, the alleged flexible shutter (276) (Fig. 69, 79) of Fogarty is a *plurality of converging and diverging leaflets* (See Fig 69). Further, the Examiner has taken the position that the scallop gap (322) between the valve (68) and the wall (4) of the tubular endroprothesis (2), as shown in Figures 82-84, corresponds to the integrated centripetal compression means of present invention. However, as illustrated, a separate lever (324) is applied at the scallop gap (322) to compress, or "crush" the valve (Col.14, lines 29-30). The scallop gap does not function to compress the valve and, therefore, does not correspond to the integrated centripetal compression means for compressing the valve recited in claim 1.

Vesely discloses a tubular endoprothesis (10, 100), and a prosthetic valve (20,109) including a deformable carrier frame (21, 110) and a plurality of leaflets (120) (Figs. 3A-3B, 4A,

4B; 12-17). However, in contrast to *resilient elastically deformable* carrier frame of the present invention, the carrier frame of Vesely consists of a plurality of *rigid, articulating members* (Col. 9, lines 13-26). Further, the leaflets (120) appear to be substantially similar to the converging and diverging valve leaflets disclosed by Garrison and Fogarty and, therefore, for at least the same reasons provided above, it is submitted that leaflets (120) of Vesley do not correspond to the flexible shutter of the present invention (See *supra*).

In view of the above, it is believed apparent that Garrison, Fogarty, and Vesely each fail to anticipate the kit recited in independent claim 1, or the method of claim 12 for using such kit. Furthermore, it is submitted that the differences are such that a person of ordinary skill in the art would have not have found the present invention obvious in view of Garrison, Fogarty, Vesely, or any of the other references of record. Therefore, claims 1 and 12, as well as 2-11 and 13-16 which depend therefrom, are believed to be patentable over the references of record.

Finally, Applicants direct the Examiner's attention to new dependent claim 16 which recites additional distinguishing features of the present invention. In particular, claim 16 specifies that the carrier frame, flexible shutter, and integrated centripetal compression means are shaped and arranged such that contacting the centripetal compression means causes the carrier frame to be compressed toward the folded position.

Accordingly, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may best be resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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A KIT FOR IMPLANTING IN A DUCT

BACKGROUND OF THE INVENTION

1. Field of the invention

The present invention relates to a kit for implanting in a duct, the kit being of the type comprising:

- a tubular endoprosthesis; and
- a prosthetic valve.

~~**Background of the invention**~~

The heart comprises two atria and two ventricles which are separated by valves. Valves are also present at the outlet from the right ventricle (pulmonary valve) and from the left ventricle (aortic valve).

These valves ensure that blood flows in one direction only, preventing a backflow of blood at the end of ventricular contraction.

Valves can suffer from diseases. In particular, they can suffer from poor opening, thereby reducing blood flow, or from not being fully leaktight, thus allowing backflow or regurgitation towards the ventricle that expels the blood flow.

These problems of regurgitation lead to abnormal dilation of the ventricle which can lead in the long run to heart failure.

2. Description of the Related Art

It is known to treat this type of disease surgically, by replacing the diseased valve. Diseased valves, and in particular the pulmonary valve at the outlet from the right ventricle, are replaced by a valve taken from a deceased donor, or by a bioprosthesis constituted by a metal frame and a shutter made of a tissue of animal origin. The shutter is permanently secured to the frame.

Prosthetic valves are also known. These are constituted by a metal frame supporting a polymer shutter. Such valves are described in particular in ~~document~~ documents WO 01/154625 and WO 01/28459.

In such prostheses, the frame is elastically deformable to a small extent only, and the shutter is constituted by a pouch. The elastically deformable frame bears against the inside wall of an organic duct, in particular the pulmonary artery coming from the right ventricle.

It ~~is~~ has been found that, after such a prosthesis has been implanted for several years, it degrades and no longer operates effectively. It is then necessary to put a new prosthesis into place.

~~Nevertheless~~However, it is not possible to withdraw the old prosthesis in an endoluminar manner, in particular because the carrier frame of the prosthesis has become secured to the heart wall, meaning that they cannot be separated without major surgical intervention for replacing the valve.

~~Object and brief summary of the invention~~SUMMARY OF THE INVENTION

An object of the invention is to propose a kit comprising a prosthetic valve that can be replaced without excessive difficulty, and without requiring major surgical intervention.

To this end, the invention provides a kit of the type specified, in which the prosthetic valve is for implanting removably in the tubular endoprosthesis ~~and comprises~~. The prosthetic valve comprises: firstly ~~a~~, a carrier frame that is radially deformable in elastic manner relative to a main axis between a deployed implanted position and a folded, implanting position, which carrier frame is urged resiliently towards its deployed position~~, and secondly~~; and secondly, a flexible shutter connected to the carrier frame and deformable between an obstruction position in which it is extended transversely, and a release position in which it is contracted transversely under the action of the flow passing through the

carrier frame~~, the valve including~~; and an integrated centripetal compression means for compressing the ~~said~~ carrier frame towards its folded position against the elastic action.

In particular embodiments, the kit includes one or more of the following characteristics:

- ~~said~~ the shutter comprises a pouch;
- the pouch includes an evacuation orifice formed in its end wall;
- the end wall of the kit is generally hemispherical;
- the centripetal compression means ~~comprise~~ comprises a clamp having at least two branches connected together in a common region, each branch being connected to ~~said~~ the shutter ~~in~~ by a connection segment, each of the branches presenting a drive segment suitable for co-operating with a complementary clamping member for centripetally compressing the carrier frame towards its folded position;
- the branches are welded together in their common region, and the carrier frame is fork-shaped, each branch being elastically deformable, the drive segments and the connection segments for connecting the branches to the shutter both being situated on the same side of the weld;
- the carrier frame has two branches;
- the carrier frame has three branches;
- the valve includes threads connecting the end wall of the pouch to each of the branches; and
- the carrier frame comprises a resilient wire mesh and ~~said~~ the centripetal compression means ~~comprises~~ a constriction strand engaged around ~~said~~ the resilient wire mesh.

The invention also provides an implanted prosthesis made from a kit as defined above, the endoprosthesis being placed against the inside surface of a duct, and the prosthetic valve being placed in ~~said~~ tubular endoprosthesis.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention can be better understood ~~on reading~~ from the following description given purely by way of example and made with reference to the drawings, in which:

- Figure 1 is a longitudinal section view of a prosthesis implanted in an organic duct, comprising a prosthetic valve in its closed state;
- Figure 2 is a ~~section view~~cross-section of the ~~Figure 1~~ prosthesis illustrated in Figure 1 along on line II-II;
- Figures 3 and 4 are views identical to Figures 1 and 2, with the prosthetic valve being in its open state;
- Figures 5 and 6 are views identical to that of Figure 1 showing successive stages in withdrawing a prosthetic valve of the invention;
- Figure 7 is a view identical to that of Figure 1 showing a variant embodiment of a prosthetic valve of the invention; and
- Figure 8 is a view identical to that of Figure 1 showing another embodiment of a prosthesis comprising a prosthetic valve.

~~More detailed description~~DETAILED DESCRIPTION OF THE INVENTION

Figure 1 shows a prosthesis of the invention that is ~~assumed~~ adapted to be implanted in a pulmonary artery 12 connected at its end 12A to the outlet from the right ventricle of the heart, in particular of a human being, and at its end 12B to the lungs.

In the invention, the prosthesis comprises an outer tubular endoprosthesis 14 having disposed therein a removable and replaceable prosthetic valve 16.

By way of example, the endoprosthesis 14 is constituted by a tubular mesh 14A embedded in a stretchable film 14B that is ~~proof against liquids~~ liquid-proof, such as an elastomer. The mesh 14A is made of stainless steel wire having spring properties, such that the endoprosthesis 14 is self-expanding. Such an endoprosthesis is commonly referred to as a "stent".

~~In known manner the~~ The endoprosthesis 14 is ~~suitable for~~ capable of deforming spontaneously from a compressed state in which it ~~presents~~ has a small diameter, to a dilated state in which it ~~presents~~ has a larger diameter, the dilated state constituting its rest state.

In its implanted state, as shown in the figures, and because of its own elasticity, the endoprosthesis 14 bears against the inside surface of the duct 12, thus forming an inside sheath for the duct.

An interchangeable prosthetic valve 16 comprises a carrier frame 22 and a deformable shutter 24 supported by the frame 22 and secured thereto. The valve is generally symmetrical about the axis X-X.

The carrier frame has means integrated therein to compress it centripetally. More precisely, the frame 22 is constituted by two branches 26A, 26B connected together at a first end 28 so as to form a clamp that is elastically deformable between a deployed position in which the two branches are spaced apart from the middle (central) axis ~~X-X~~X-X, and a folded position in which the two branches are moved towards the middle axis X-X.

The two branches 26A, 26B are generally symmetrical about the middle axis X-X that coincides with the axis of the duct once the prosthesis has been implanted.

The length of the branches measured along the axis X-X lies in the range 2 centimeters (cm) to 4 cm, and is preferably equal to 3 cm.

Each branch 26A, 26B has a bearing segment 30A, 30B for bearing against the endoprosthesis 14. Each bearing segment is constituted by a rectilinear segment extending generally along a generator line of the endoprosthesis 14 when the frame is deployed.

The length of the bearing segments lies in the range 1 cm to ~~3 cm~~3 cm, and is preferably about 2 cm.

The bearing segments 30A, 30B are extended by drive segments 32A, 32B that converge towards each other onto the

connection point 28. These segments are generally inclined relative to the middle axis X-X.

The drive segments 32A, 32B are generally curved and present a center of curvature lying outside the space defined between the two branches. Thus, the segments 32A and 32B bulge towards the inside of the clamp.

The shutter 24 is constituted by a flexible pouch 34 having a generally circular opening 35 on the axis X-X when the pouch is inflated.

The pouch 34 ~~presents~~ has a generally cylindrical skirt 36 extended by a generally hemispherical end wall 38. The end wall 38 ~~presents~~ has an orifice 40 of a diameter that is small relative to the section of the opening 35.

By way of example, the pouch 34 is made of polyurethane or out of a biological material (bovine pericardium).

By way of example, the height of the skirt 36 is equal to 4 millimeters (mm) or 5 mm, and it preferably lies in the range 2 mm to 5 mm.

The pouch 34 is connected to the two bearing segments 30A, 30B by adhesive or by any other appropriate means along the length of the generator lines of the skirt 36.

Advantageously, the pouch 34 is connected to the two branches 26A, 26B in such a manner that the two half-skirts defined on either side are of lengths that are slightly different.

Finally, the end wall 38 is connected by threads 42 to the drive segments 32A, 32B of the two branches of the carrier frame so as to prevent the pouch from being turned inside out by invagination.

When implanted, such a prosthetic valve operates as follows. At the end of expulsion from the right ventricle, when the ventricle increases in volume, the blood flow is sucked into the duct 12 from the end 12B towards the end 12A. The blood then fills the pouch 34 which presses against the endoprosthesis 14, as shown in Figures 1 and 2, thereby

closing off the organic duct 12 ~~in~~ in a substantially leaktight manner.

During circulation of the blood, the orifice 40 allows a constant small flow of blood to pass through the pouch 34, thus preventing a blood clot from forming at the bottom of the pouch 34 as a result of possible stagnation of the blood.

In contrast, during contraction of the right ventricle, blood flows from the end 12A towards the end 12B. As shown in Figures 3 and 4, the pouch 34 is urged outwards from its end wall 38, thereby causing the pouch to flatten. The blood is thus free to flow along the duct on either side of the pouch.

The difference in length between the two portions of the skirt disposed on either side of the two arms ensures that in the position shown in Figures 3 and 4, the two half-skirts do not press against each other and do not become pressed together definitively against the endoprosthesis 14.

In order to implant the prosthesis in the duct 12, ~~use is made of~~ a kit of the invention comprising the endoprosthesis 14 and the prosthetic valve 16 is used.

Initially, the endoprosthesis 14 is implanted in the duct 12 by an endoluminal technique.

Thereafter, the valve 16 is implanted by the endoluminal technique inside the endoprosthesis 14.

After such a prosthesis has been implanted, the wall of the organic duct bonds progressively with the endoprosthesis 14. However, the endoprosthesis 14 constitutes a sheath ~~constituting~~ which acts as a screen between the prosthetic valve 16 and the wall of the duct 12, thus avoiding agglomeration of the organic duct and the prosthetic valve. This means that it is possible to withdraw the prosthetic valve.

In particular, since the prosthetic valve is fitted with centripetal compression means, it can be returned to its compressed state and removed in transluminal manner.

More precisely, and as shown in Figure 5, in order to withdraw the prosthetic valve, a catheter 60 is inserted via

the right atrium and the right ventricle and is placed in register with the end 28 of the clamp-forming carrier frame.

A traction tool 62 is conveyed along the catheter 60. At its end, the tool has a jaw 64 suitable for taking hold of the end 28 of the clamp. When the open end, referenced 66, of the catheter comes into contact with the drive segments 32A, 32B, the carrier frame is pulled progressively into the duct 60. By a camming effect, the two arms 26A, 26B are moved towards each other and the prosthetic valve is brought progressively into its compact state and is inserted into the catheter 60, as shown in Figure 6. The catheter 60 containing the prosthetic valve is then extracted from the human body.

A new catheter containing a new prosthetic valve is then inserted into the human body and the valve is released by performing the above-described operations in reverse order. In particular, the prosthetic valve is extracted progressively from the catheter 60 by being pushed from its end 28. Under the resilient action of the clamp constituted by the carrier frame 22, the prosthetic valve is deployed and bears radially against the tubular endoprosthesis 14.

Figure 7 shows a variant embodiment of the prosthetic valve of the invention.

In this embodiment, the carrier frame, referenced 122, is constituted by a clamp comprising three arms 126A, 126B, 126C, each in the form of an arm 26A, 26B. These arms are regularly distributed around the longitudinal axis X-X of the prosthesis.

As before, these arms are suitable for bearing against the endoprosthesis 14, and they are connected together at a connection end 128.

In yet another variant, as shown in Figure 8, the prosthetic valve 216 comprises a resilient tubular wire mesh 222 and a shutter-forming pouch 224 identical to the pouch 34. The pouch 224 is connected around its open periphery to the tubular mesh at two or three points.

The prosthetic valve also includes a constriction strand 226 permanently engaged in the various loops defined by the endoprosthesis 216 and extending around its circumference. This strand forms a closed loop. It is long enough to allow the valve to expand. This strand forms the centripetal compression means. Applying traction to the strand, e.g. by means of a clamp, causes the carrier frame 222 to be constricted, thus enabling the prosthetic valve to be withdrawn after it has been engaged in a catheter.

In another variant, the kit is implanted in a prosthetic duct 12, in particular a flexible tube, which has ~~itself~~ previously been implanted in an organic duct or used as a replacement therefor.

The endoprosthesis 12 is then placed by the endoluminal technique so as to bear against the inside wall of the flexible tube.

In another variant, the kit comprises an endoprosthesis 12 constituted by a rigid ring. The length of the ring is substantially equal to the length of the bearing segments 30A, 30B of the prosthetic valve 16.

This type of kit is used when replacing internal heart valves, in particular the tricuspid valves and the mitral valves.

In order to implant the kit in the heart, the ring already fitted with the prosthetic valve 16 is implanted initially by the surgical technique in the heart, to replace a defective heart valve.

When the prosthetic valve 16 becomes defective, it can also be replaced by the endoluminal technique, as described above.

A B S T R A C T

~~The~~ A kit ~~comprises~~ for implanting in a duct, which includes a tubular endoprosthesis and a prosthetic valve is disclosed. ~~which comprises~~ The prosthetic valve includes a carrier frame that is radially deformable in elastic manner relative to a ~~main~~ central axis of the tubular endoprosthesis between a deployed, implanted position, and a folded, implanting position. The carrier frame is urged elastically towards its deployed position. A flexible shutter is connected to the carrier frame. ~~It~~ The shutter is deformable between an obstruction position in which it is extended transversely, and a release position in which it is contracted transversely under ~~the action of the flow flowing~~ to allow a fluid to flow through the carrier frame. The carrier frame also includes an ~~means~~ integrated ~~therein~~ centripetal compressing mechanism for centripetally compressing the ~~said~~ carrier frame towards ~~its~~ folded position ~~against the elastic action~~.